EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), *Plaintiffs*, v. DEREK BROWN, in his official capacity as ATTORNEY GENERAL OF THE STATE OF UTAH, and JON PIKE, in his official capacity as INSURANCE COMMISSIONER OF THE STATE OF UTAH, *Defendant*.	Case No.2:25-cv-00271 Judge David Barlow Magistrate Judge Daphne A. Oberg

DECLARATION OF EDWARD SCHEIDLER

I, Edward Scheidler, declare as follows in support of Plaintiff's Motion for a Preliminary Injunction in the above-captioned action:

1. I am over the age of 21, under no disability, and competent to testify to the matters contained in this declaration.

2. I am the Head of the 340B Center of Excellence at AbbVie Inc. ("AbbVie") I have worked at AbbVie since 2004 and been responsible for AbbVie's 340B program since 2017. My responsibilities include regularly engaging with the purchasers of AbbVie's pharmaceutical

products concerning AbbVie's participation in the federal 340B program, including with respect to AbbVie's relationships with commercial pharmacies (many of which are so-called "contract pharmacies"). I am familiar with the conditions of participation in federal health care programs, such as Medicare and Medicaid.

3. AbbVie Inc. and the other Plaintiffs named in *AbbVie, Inc. et al. v. Brown*, No.2:25-cv-00271-DBB, are currently parties to Pharmaceutical Pricing Agreements ("PPAs") executed with the United States Department of Health and Human Services ("HHS"). I understand the terms of the PPAs to be set by statute and non-negotiable. A true and correct copy of an executed PPA is attached hereto as Exhibit A as an example. *See* Ex. A (Pharmaceutical Pricing Agreement). The entity who executed the PPA at Exhibit A later merged into Plaintiff, Allergan Sales, LLC, a subsidiary of AbbVie Inc. (The PPAs relevant to the other six Plaintiffs are virtually identical by terms and obligations imposed.)

4. On April 17, 2023, AbbVie implemented an initiative under which AbbVie continued to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute but clarified that it would no longer indiscriminately accept requests to transfer or otherwise ship 340B discounted drugs to an unlimited number of contract pharmacies serving hospital covered entities. A true and correct copy of the April 17 initiative is attached as Exhibit B. True and correct copies of subsequent updates to the policy language, issued on April 30, 2024 and February 27, 2025, are attached as Exhibit C and D, respectively. *See* Ex. B, Ltr. from C. Compisi to 340B Covered Entities (March 29, 2023); Ex. C, Ltr. from C. Compisi to 340B Covered Entities (April 30, 2024); Ex. D, Ltr. from E. Scheidler to 340B Covered Entities (Feb. 27, 2025). AbbVie's policy in no way affects patient access to drugs. AbbVie is committed to ensuring that each hospital covered entity has at

least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's discounted 340B drugs to qualifying patients.

5. Under AbbVie's current policy, AbbVie facilitates the shipment of orders of 340B priced medicines to one contract pharmacy location if the hospital covered entity does not have an in-house pharmacy, submits limited claims data on 340B utilization for that contract pharmacy, and the contract pharmacy is located within 40 miles of the HRSA registered covered entity. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative. Federal Grantees[1] may place orders for direct delivery to an unlimited number of contract pharmacies as long as the Grantee covered entity registers with 340B ESP™—a web-based platform made available to covered entities at no cost—and submit claims data. Under this policy, AbbVie continues to make its products available at 340B-discounted prices in unlimited quantities to *all* covered entities, and certain contract pharmacies. AbbVie has stopped providing 340B discounted drugs to an unlimited number of contract pharmacies for hospital covered entities.

6. In my role at AbbVie, I have acquired deep knowledge of and experience with the functioning of all facets of the 340B Program, including covered entities' use of contract pharmacies, the conditions of participation set out in the federal PPA, how the program operates in practice, and how it affects AbbVie's business. In particular, I am familiar with the "replenishment model" that contract pharmacies use to cause covered entities to place orders for 340B discounted drugs as well as the mechanisms by which 340B discounts are applied. In the course of my job, I have regular conversations with contract pharmacies and covered entities

[1] "Grantee" covered entity types are listed in 42 U.S.C. § 256b(4)(A)–(K).

regarding the 340B program, and I work with them to address any disputes that may arise, or clarifications requested, regarding AbbVie's 340B policies.

7. I have reviewed Utah's S.B. 69 and understand it to be similar to legislation enacted in at least eleven other states, the constitutionality of which is currently being challenged by pharmaceutical manufacturers in federal courts. I wish to clarify and expand on several points based on my experience and my understanding of the Utah bill and its context:

a. S.B. 69 repeatedly uses the language "340B drugs." *See* S.B. 69, § 1(2)(a)(ii)–(iv), (2)(b)(i)–(ii). To clarify: there is no such thing as a "340B drug." There are only drugs—identical in composition and quality—offered for purchase at different price points, including at the 340B-ceiling price. Just as no one refers to a "WAC drug" or a "GPO drug" or a "Purchase Discount drug," the label "340B drug" is a misnomer.[2] The product does not change; only the commercial terms of the transaction vary. S.B. 69's language presumes a (faulty) distinction where none exists.

b. AbbVie's policy has no impact on patient access to critical medication. AbbVie's policy in no way restricts or limits any pharmacy's ability to order drugs—AbbVie will deliver its drugs (provided they are not in shortage) to any pharmacy, anywhere. A Utahn can present a prescription at any pharmacy and receive the medication; no customer must travel a significant distance to fill a prescription. AbbVie is in no way limiting the availability of medications in

[2] The Wholesale Acquisition Cost (WAC) is the list price set by manufacturers for sales to wholesalers. Group Purchase Organizations (GPOs) negotiate discounted prices on behalf of healthcare providers. "Purchase discounts" refer to other negotiated or volume-based discounts available in commercial contracts. These terms reflect pricing mechanisms—not distinct or different types of drugs.

Utah or elsewhere. Whether a patient can obtain a prescription medication is instead dependent on whether (1) the pharmacy chooses to stock the drug and (2) the patient's health insurance plan will cover it. For these reasons, the availability of 340B *pricing* has no bearing on patient access or a drug's availability.

c. For covered entities employing the replenishment model described below, the geographic location of the hospital has no effect on the amount paid by customers. A customer from Price, UT would pay full commercial price (i.e., whatever would be stipulated under that patient's insurance plan—hence why a pharmacy or doctor's office always asks for an insurance card first) for a drug whether she went to a local drugstore around the corner or a CVS in Salt Lake City, UT.

8. Under the "replenishment model," contract pharmacies dispense drugs to 340B and non-340B patients out of their general inventories. They do not maintain physically segregated inventories of 340B-priced drugs. Nor do most contract pharmacies attempt to determine prior to sale whether the patient is eligible for a 340B-discounted drug. In other words, in almost all instances, contract pharmacies order AbbVie-manufactured drugs and dispense them to their customers at full price without knowledge as to whether, at the time of dispensing, that patient is a 340B-eligible patient.

9. Pharmacies purchase AbbVie products for their general inventories at market prices. After a particular quantity of a particular drug is dispensed to pharmacy customers, the pharmacy (either itself or through a Third-Party Administrator "TPA" with which it contracts) determines which *prior* dispensing events should be linked with 340B eligibility. This

determination is typically made via the contract pharmacy's own criteria, without any involvement from the covered entities. The contract pharmacy's criteria may include prior patients, who no longer receive the 340B-discounted drugs at the pharmacy but are included under a "once-a-patient-always-a-patient" approach, so the covered entity and its pharmacies are able to maximize the arbitrage profits from the 340B program. Some covered entities and contract pharmacies sometimes work together to set the criteria for 340B "patient" eligibility. For example, I am aware that some contract pharmacies use a "set it and forget it" process, whereby they agree on certain criteria with the TPA at the time of contracting and never revisit those criteria. Conversely, sometimes covered entities change their "patient definition" and reprocess, retroactively, historical data to determine additional eligible dispensing events for those time frames based on *new* criteria.

10. After identifying the purported 340B-eligible transactions, the contract pharmacy (typically through a TPA) instructs the covered entity associated with the patient to place an order of *additional* quantities of that drug at the discounted 340B price to "replenish" the contract pharmacy's inventory of non-340B-discounted drugs. However, I am not aware of any instances where the covered entity directly places replenishment orders for a contract pharmacy dispense. Rather, in my experience, the order is typically generated and submitted by the contract pharmacy (either itself or through a TPA) using a third-party covered entity's purchasing account information. I am aware of at least one situation where a contract pharmacy placed a replenishment order with AbbVie; and when AbbVie later asked the covered entity about this order, the covered entity stated that it did not know that a replenishment order had been placed.

11. It is through this mechanism that AbbVie must extend the 340B discount on units given to contract pharmacies to replace inventory purchased at non- discounted prices that may—if the TPA's algorithm works correctly—have been dispensed to patients of a covered entity.

12. When a contract pharmacy places an order on behalf of a covered entity, AbbVie usually does not ship its 340B-discounted "replenishment" drugs to the covered entity.[3] While the covered entity makes the purchase, replenishment product is shipped directly from the wholesaler to the contract pharmacy. Within the industry, this practice is referred to as a "Bill To/Ship To" order. This means the wholesaler bills the covered entity but ships to the contract pharmacy. These shipments of 340B-priced drugs to contract pharmacies are not based on orders needed for specific 340B-eligible patients based on actual or projected future need.

13. I do not understand covered entities to maintain legal title to AbbVie drugs while they are held in a contract pharmacy's general inventory prior to being identified, post-sale, as 340B-linked drugs. Instead, at the time of sale to a patient, a unit of drugs is owned by the contract pharmacy itself.

14. I understand that, as a result of the replenishment model, patients continue to pay full price at the point of sale or dispensing, or their insurer or other payment plan does. Note then that when that drug is "replenished" at the 340B discounted price, that creates a difference between the full price paid by customers at the pharmacy counter and the discounted price AbbVie offers to covered entities, known as "spread." The contract pharmacy and covered entity split that spread pursuant to the terms of the agreements between them, usually some percentage is retained by the pharmacy. This phenomenon has been well-documented in multiple sources, ranging from the U.S. Department of Health and Human Services Inspector General to newspaper reporters for major outlets.[4]

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[3] AbbVie does ship drugs to covered entity-owned pharmacies, as well as covered entities' in-house pharmacies.

[4] *See* HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: Contract Pharmacy Arrangements in the 340B Program (2014) ("HHS Report"), at 2, https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, WALL ST. J. (Sept. 10, 2020),

15. To provide an example of the replenishment model in practice, I will describe the process via a hypothetical sale of "Drug A," premised on data in AbbVie's internal invoicing system for 340B orders. I assume Drug A has a commercial price of $100 per unit, and is subject to a discount rate of 99% under AbbVie's PPA. That 99% difference yields a per-unit 340B price of $1.00. In other words, the difference between the commercial price and 340B-price is $99.00. A CVS Pharmacy in Salt Lake City, UT orders 10 units of Drug A at the $100.00 commercial price, per unit, for a total of $1,000 in cost. The CVS Pharmacy then resells the product at a mark-up price of $120.00 per unit of Drug A.

a. Over the next month, ten customers receive prescriptions for Drug A, have them filled at the CVS Pharmacy, and pay $120 per unit either out-of-pocket (i.e., a $25 copayment) or via private insurance coverage for which they pay a premium. The CVS receives, in total $1,200 from the 10 customers who purchased Drug A, recouping both the initial commercial price and $200 in profit. (I assume some level of mark-up by the CVS over the commercial acquisition cost when transacting with customers at the pharmacy counter.)

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https://www.wsj.com/articles/the-federal-program-that-keeps-insulin-prices-high-11599779400 (explaining that "almost half the U.S. pharmacy industry now profits from the 340B program, which is designed as a narrow support to certain hospitals," while patients "don't benefit" and "are expected to pay . . . full out-of-pocket costs," even though manufacturers have "practically given the product away"); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, IQVIA, at 12, https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf ("The 340B Drug Discount Program as it exists today is a complex system of arbitrage . . . in which most vulnerable patients at contract pharmacies do not get drug discounts."); Lin JK, et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum (2022), at 2, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530 (finding that contract pharmacy growth from 2011–2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

b. Later, the TPA of CVS Pharmacy (usually it is Wellpartner, owned by CVS), calculates how many of those ten units of Drug A they believe were dispensed to a 340B patient of a specific Covered Entity under contract with that particular CVS location. Neither I, nor anyone at AbbVie, have any insight into or understanding of how this determination is made or what factors are considered. I understand, generally, that these determinations are often not accurate. Their criteria for determining whether a customer was a 340B patient can include factors like the identity of the prescriber or how long ago the patient last received a prescription from a 340B-eligible covered entity. As explained above, I understand that some contract pharmacies have a "once-a-patient-always-a-patient" model, which includes any customer who has *ever* received a prescription from a 340B covered entity or prescriber.

c. In our example, let us assume that the CVS Pharmacy and its TPA determine five of the ten customers who purchased Drug A were 340B-eligible patients. The CVS Pharmacy and its TPA then notify the covered entity to order five units of Drug A for the CVS Pharmacy to "replenish" the five full-priced units of Drug A that the CVS Pharmacy previously purchased and dispensed to 340B patients.

d. As explained above, those five 340B patients have already paid full price (or their insurer has) for their unit of Drug A at the $120 price. I do not understand that contract pharmacies retroactively reimburse patients for the 340B-eligible price after the fact. If they did, AbbVie's policy would not in any way prohibit a covered entity's election to undertake that practice.

e. AbbVie or its wholesaler receive the covered entity's order for five units of Drug A and ships them to the CVS Pharmacy in the same package or on the same pallet as commercially-purchased units of Drug A and other drugs being sent to the CVS Pharmacy via a commercial order.

f. There is no way to discern which units of Drug A are the five units sold at the 340B price. They are not packaged differently, labeled differently, or shipped separately or in a different kind of box (either by color, labeling, or other demarcation). One received by the contract pharmacy, they are placed into the general inventory and dispensed to any customer who walks in the door, 340B-eligible or otherwise. The only difference between a unit of Drug A shipped for "replenishment" and other units of Drug A *is the price* AbbVie receives for the shipment of its drugs. Placing 340B replenishment orders has no effect on how AbbVie drugs are transported or delivered.

g. The CVS receives the five units of Drug A at the 340B price and, as a matter of accounting, adjusts the previous paid price for those five units down to the cost of the 340B price, $1.00. The CVS then splits the differential, $495, between itself and the covered entity at some percentage. If we assume it is 70/30 in favor of the covered entity, then CVS keeps $148.50 and pays the covered entity $346.50. The patient who paid the full $120 (or their $25 copayment) receives no discount.

16. It is my understanding that AbbVie has no obligation to contract pharmacies under the 340B program. I do not understand contract pharmacies, like CVS, to be agents of covered entities in Utah or elsewhere.

17. When AbbVie changed its 340B contract pharmacy policy, a large commercial specialty pharmacy customer requested a meeting with AbbVie to discuss "its" 340B discount. AbbVie refused to meet with this pharmacy, explaining that it is not entitled to place orders at the 340B price, and that it needed to reach out to its respective covered entities if it had concerns with those entities' access to 340B discounts.

18. In addition to the "replenishment model," I understand that some covered entity stakeholders are converting to what is known as a "credit," "non-inventory replenishment," or "inventory synchronization model." Under this emerging model, contract pharmacies attempt to create a credit against their non-340B WAC-priced orders when they identify covered entity "patients" at contract pharmacies. At the very least, the emergence of this model evidences that 340B discounts are sometimes provided without even the suggestion that covered entities maintain legal title or that contract pharmacies function as legal agents subject to the dictates of covered entities.

19. Additionally, I am also aware that some contract pharmacies and covered entities use a "*pre*-plenishment model." Under that model, a covered entity and contract pharmacy predict, based on average data, how many prescriptions of a particular drug they think are likely in a given month and order those drugs ahead of time to "pre-plenish" the contract pharmacy's stock. That practice is (1) unmoored from any actual 340B eligible dispensing event, and (2) misunderstands the reality that often times prescriptions are not filled or are filled elsewhere, making any such "prediction" of how many 340B-eligible customers are likely to come in nearly impossible.

20. I understand that Utah, like several other states, has enacted legislation purporting to impose state-law obligations on manufacturers, like AbbVie, as a condition of their participation

in the federal 340B program. I further understand that Utah's law, S.B. 69, requires AbbVie to cooperate with an unlimited number of contract pharmacy arrangements.

21. As a manufacturer, AbbVie relies on revenues generated from sales of its drugs to recoup the high costs of developing new, better drugs. While AbbVie willingly complies with its obligations under the federal 340B program to help provide low-cost drugs to at-risk patients, AbbVie's ability to sell its products at non-340B prices for transactions that fall outside the requirements of the federal 340B statute is important to its ability to invest in developing new drugs with the goal of improving patients' lives.

22. Requiring cooperation with unlimited numbers of contract pharmacy arrangements in Utah, as I understand Utah's S.B. 69 to require, would have a significant effect on the volume of AbbVie drugs subject to 340B pricing. When AbbVie first revised its 340B policy to prohibit sales to unlimited contract pharmacies in April 2023, AbbVie experienced a significant reduction in the volume of drugs for which 340B pricing was requested. Notably, the policy did not change or otherwise affect the way 340B-priced drugs are delivered or shipped to contract pharmacies.

23. Because S.B. 69 requires AbbVie to provide its drugs at steeply discounted 340B prices to an unlimited number of contract pharmacy arrangements, AbbVie will face the threat of millions of dollars in forced unnecessary discounts each year as a result of S.B. 69. AbbVie estimates that in 2024, compliance with state contract pharmacy laws cost approximately $33.1 million in Mississippi and $35 million in Missouri.

24. Once 340B discounts are given, it is my understanding that there is no way for a covered entity or contract pharmacy to automatically refund AbbVie for unlawfully received discounts if Utah's statute is subsequently invalidated.

25. This lost revenue will negatively impact AbbVie's business model and affect its ability to invest in future products. This will in turn impact the public and vulnerable patients who desperately need innovative drugs and new treatments. These harms are irreparable because once research and development opportunities are lost or delayed, it is impossible to recoup that lost investment.

26. S.B. 69 threatens to impose significant monetary penalties in the case of a violation, including up to criminal penalties. These penalties pose a significant legal, operational, and reputational risk to AbbVie.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct; in witness whereof, I have caused my signature to be hereunto affixed.

Executed on this 10th day of April 2025.

By: 

Edward Scheidler

EXHIBIT A

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)

In accordance with the guidance found in the May 7, 1993, *Federal Register*, (link here) Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage.

Manufacturer is defined in the guidance listed above, as follows:
The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in –

> (1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or
>
> (2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the PHS drug pricing agreement.

Please print the attached Pharmaceutical Pricing Agreement (PPA) in its entirety and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs Branch (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the document once it is counter-signed by the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration.

If you have any questions, please contact the 340B Prime Vendor at 1-888-340-2787 or via email at ApexusAnswers@340BPVP.com.

PHARMACEUTICAL PRICING AGREEMENT

(hereinafter referred to as the "Agreement")
Between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
(hereinafter referred to as the "Secretary") and
THE MANUFACTURER
Identified in Section IX of this Agreement
(hereinafter referred to as the "Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer for purposes of section 602 of the Veterans Health Care Act of 1992, Public Law No. 102-585, which enacted section 340B of the Public Health Service Act (hereinafter referred to as "the Act"), 42 U.S.C. 256b, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in the Act and section 1927(k) of the Social Security Act, as interpreted and applied herein:

(a) **"Average Manufacturer Price (hereinafter referred to as the "AMP")"** means the average unit price paid to the Manufacturer for the drug in all States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under the distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act), which reduce the actual price paid. It is calculated as a weighted average of each drug of prices for all the Manufacturer's package sizes for each calendar quarter. Specifically, it is calculated as net sales divided by the numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangements. The AMP for a calendar quarter must be adjusted by the Manufacturer, if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) **"Best Price"** has the meaning given it in section 1927(c)(1)(C) of the Social Security Act, and section I(d) of the Medicaid Rebate Agreement.

(c) **"Bundled Sale"** refers to the packaging of drugs of different types where the total price for the package is less than the purchase price of the drugs, if purchased separately.

(d) **"Covered Drug"** means an outpatient drug as set forth in section 1927(k) of the Social Security Act. For purposes of coverage under the Agreement, all covered outpatient drugs are identified by the NDC number.

(e) **"Covered Entity"** means:

(1) certain Public Health Service grantees, "look-alike" Federally Qualified Health Centers and disproportionate share hospitals as described in section 340B(a)(4) of the Act; and

(2) in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall not be considered a covered entity unless it meets the requirements of section 340B(a)(4)(L) of the Act, as determined by the Secretary.

(f) **"Manufacturer"** has the meaning as set forth in section 1927(k)(5) of the Social Security Act except that, for purposes of the Agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the covered outpatient drug. The term includes:

(1) any Manufacturer who sells covered outpatient drugs to covered entities, whether or not the Manufacturer participates in the Medicaid rebate program; and

(2) any contractors which fulfill the responsibilities pursuant to the Agreement, unless excluded by the Secretary.

(g) **"Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration)"** means the agency of the Department of Health and Human Services having the delegated authority to administer the Medicaid and Medicare Programs.

(h) **"Medicaid Rebate Program and Medicaid Rebate Agreement"** mean, respectively, the program, and a signed agreement between the Secretary and the Manufacturer, to implement the provisions of section 1927 of the Social Security Act.

(i) **"National Drug Code (NDC)"** means the identifying drug number maintained by the Food and Drug Administration (FDA). For purposes of the Agreement, the NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specified product or formulation), and package size code when reporting requested information.

(j) **"Over the Counter Drug"** means a drug that may be sold without a

prescription and which is prescribed by a physician (or other persons authorized to prescribe such drugs under State law).

(k) **"Quarter"** means a calendar quarter unless otherwise specified.

(l) **"Rebate Percentage"** means an amount (expressed in a percentage) equal to the average total rebate required under section 1927(c) of the Social Security Act with respect to each dosage, form, and strength of a single source or innovator multiple source drug during the preceding calendar quarter; divided by the AMP for such a unit of the drug during such quarter.

(m) **"the Secretary"** means the Secretary of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(n) **"Unit of the Drug"** means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Section II of the Agreement.

(o) **"Wholesaler"** means any entity, having a wholesale distributor's license, to which a Manufacturer sells the covered outpatient drug, but which does not relabel or repackage the covered outpatient drug.

II. MANUFACTURER'S RESPONSIBILITIES

Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:

(a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage;

(b) for multiple source, noninnovator multiple source, and over the counter drugs, the AMP is reduced by 11%, as described in 1927(c)(3)(B)(ii) of the Social Security Act;

(c) for those Manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs, to submit to the Secretary upon request, a list of such covered outpatient drugs, and the AMP,

baseline AMP, and the Best Price of such covered outpatient drugs;

(d) to retain all records that may be necessary to provide the information described in paragraph (c) of this section for not less than 3 years from the date of their creation;

(e) to afford the Secretary or his designee reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement;

(f) to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate Agreement on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement; and

(g) to participate in the HRSA Prime Vendor Program as provided by section 340B(a)(8) of the Act unless otherwise agreed to by the Secretary.

III. SECRETARY'S RESPONSIBILITIES

Pursuant to the requirements under section 340B of the Act, the Secretary agrees to the following:

(a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis;

(b) with respect to a covered entity that bills Medicaid using a cost basis for drug purchases, to require the entity to submit its pharmacy Medicaid provider number. The Secretary shall provide respective State Medicaid agencies with the list of such entities and their Medicaid provider numbers. Based on these provider numbers, the State agencies will create an exclusion file which will exclude data from these entities when generating Medicaid rebate requests.

(c)to require each covered entity to retain purchasing and dispensing records of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under Title XIX of the Social Security Act for not less than 3 years.

IV. DISPUTE RESOLUTION

(a) If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A), the Manufacturer can access the elective dispute resolution process in the following manner:

(1) The Manufacturer shall attempt in good faith to resolve the matter with the covered entity.

(2) If unable to resolve the dispute, the Manufacturer may provide written notice of the discrepancy to the Secretary.

(3) The Secretary, at his discretion, will initiate an informal dispute resolution process.

(4) If the Secretary finds, after conclusion of the dispute resolution process, that the entity is in violation of such prohibitions, the entity shall be liable to the Manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug as described in section II(a) of the Agreement. Pursuant to section 340B(a) (4) and (5) a covered entity also could be removed from the list of eligible entities.

(b) The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary. Upon presentation of appropriate information documenting the entity's ineligibility, the Secretary shall take such steps as necessary to carry out his responsibilities under paragraph III(a) of the Agreement.

(c) If the Secretary believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate the Agreement. A Manufacturer who does not have an agreement with the Secretary pursuant to the Act, will no longer be deemed to meet the requirements of section 1927(a)(5)(A) of the Social Security Act.

(d) A covered entity's failure to comply with the audit requirement pursuant to section 340B(a)(5)(C) of the Act shall be cause for the Manufacturer to notify the Secretary or his designee and for the Secretary to initiate the informal dispute resolution process. Such action will not relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of

the Act and the Agreement.

(e) Nothing in this paragraph shall preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law.

V. CONFIDENTIALITY PROVISIONS

(a) Information disclosed by the Manufacturer in connection with the Agreement, except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer, except as necessary to carry out the provisions of section 340B of the Act, and to permit review by the Comptroller General.

(b) The Manufacturer will hold audit information obtained from the covered entities confidential. If the Manufacturer receives further information on such data, that information shall also be held confidential. Nothing in this paragraph shall preclude the Manufacturer from making such information available to the Secretary to enable the Secretary to carry out the provisions of section 340B of the Act.

VI. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of the Agreement, the Agreement shall be effective for an initial period of 1 year, beginning on the date specified in section IX of the Agreement. It shall be automatically renewed for additional successive terms of 1 year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the applicable period.

(b) The Manufacturer may terminate the Agreement for any reason. Such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, and the ending date of the term of the Agreement, if notice has been given 90 days before the end of the term.

(c) The Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide the Manufacturer, upon request, the opportunity to participate in an informal dispute resolution process concerning the termination, but such a process shall not delay the effective date of the termination. Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the Secretary, except to the extent that there is a violation of the provisions of the Agreement.

(d) If the Agreement is not renewed or is terminated, the Manufacturer is prohibited from entering into another Agreement as provided in section 340B of the Act until a period of one complete calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect the ceiling price under paragraph II(a) for any covered outpatient drug purchased before the effective date of termination.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of the Agreement will be sent in writing.

(1) Notice to the Secretary will be sent to:

Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane Mail
Stop 8W03A
Rockville, Maryland 20857

(2) Notice concerning data transfer and information systems issues is to be sent to the same address as listed above (section VII(a)(1) of this Agreement).

(3) Notice to the Manufacturer will be sent to the address as provided with the Agreement and updated upon Manufacturer notification to the Secretary at the address in the Agreement.

(b) The Manufacturer will be permitted to audit the records of each covered entity

(1) that directly pertain to the entity's compliance with the prohibition on

(A) the resale or other transfer of covered outpatient drugs to persons not patients of the entity, section 340B(a)(5)(B), and

(B) duplicate discounts pertaining to the rebate under section 1927 of the Social Security Act, section 340B(a)(5)(A);

(2) in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits; and

(3) at the Manufacturer's expense.

(c)No provision in the Agreement shall prohibit the Manufacturer from charging a price

for a drug that is lower than the ceiling price as described in section II(a) of the Agreement.

(d) In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner.

(e) Nothing in the Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

(f) Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, or Federal laws, or State laws.

(g) The Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(h) Except for changes of addresses, the Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(i) In the event that a due date falls on a weekend or Federal holiday, items will be due on the first business day following that weekend or Federal holiday.

VIII. EFFECTIVE DATE

The Agreement will be effective upon signing but will in no way alter the effective date upon which drug discounts were to be given to covered entities under any previously signed Pharmaceutical Pricing Agreement between the Secretary and the Manufacturer.

IX. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ Date: _____

Title: Associate Administrator
Healthcare Systems Bureau
Health Resources and Services Administration

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments, or other changes to this pricing agreement.

By: _____ Printed Name: Rob Michael
(Signature)

Title: Vice Chairman and CFO Date: 5/31/2022

Phone Number: 847-938-0927 Ext.___ FAX Number: _____

e-Mail Address: robert.michael@abbvie.com

Manufacturer Labeler Code(s): 61168

Name of Manufacturer: Kythera Biopharmaceutical Inc (An AbbVie Company)

Manufacturer Address: 1 N Waukegan Rd
N. Chicago, IL 60064

Contact Person: April Gerzel

Title: Director, Public Payer Markets

Phone Number: 847-937-5979 Ext._____ FAX Number: _____

e-Mail Address: april.gerzel@abbvie.com

EXHIBIT B

abbvie

March 29, 2023

Dear 340B Covered Entity,

AbbVie is updating its 340B program integrity initiative. The updated initiative is designed to address persistent abuses of the 340B program, including diversion and inappropriate duplicate discounting. AbbVie's updated initiative will *not* block access to 340B priced medicines for any eligible covered entity and patients will continue to have uninterrupted access to AbbVie's medicines.

Effective April 17, 2023, AbbVie will decline to facilitate bill to/ ship to orders for all hospital covered entities for 340B-priced medicines. This limitation on bill to/ ship to orders in AbbVie's new policy is aligned to AbbVie's standard commercial sales conditions for non-340B customers. Accordingly, hospital covered entities will no longer be permitted to direct delivery of AbbVie's 340B priced medicines to contract pharmacies. AbbVie's 340B integrity initiative will continue to honor bill to/ ship to requests to contract pharmacies for grantee covered entities.

What is not changing? Patients will continue to have uninterrupted access to AbbVie medicines. All covered entities will continue to be able to purchase 340B priced medicines and have them delivered to locations properly registered as a 340B covered entity or child site on the HRSA database. Covered entities will be offered, and may purchase, as much AbbVie medicine at the 340B price as desired, provided it is shipped to the covered entity location. Grantee covered entities will still be permitted to utilize contract pharmacies.

What is changing for *hospital covered entities*? Starting April 17, 2023, except for the limited exceptions described below or in the attached FAQs, hospital covered entities will no longer be eligible to place bill to/ ship to replenishment orders of 340B priced medicines for contract pharmacies.

A hospital covered entity *without* an in-house outpatient pharmacy may designate one contract pharmacy location. AbbVie will facilitate bill to/ ship to orders of 340B priced medicines to that location only; provided that, (i) the covered entity submits limited claims data on 340B utilization for such contract pharmacy location and (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

Even if your hospital covered entity had previously designated a contract pharmacy location under AbbVie's existing policy, you will need to access 340B ESP™ and designate one contract pharmacy location for AbbVie's updated policy. Please do so prior to April 9, 2023. For details on accessing the exceptions to this policy, please see the attached FAQs.

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What is changing for *federal grantee covered entities*? There is **no change** for federal grantee[1] covered entities, such as community health centers, federally-qualified health centers and Ryan White clinics. Federal grantee covered entities will continue to be eligible to place bill to/ ship to replenishment orders of 340B priced drugs for their contract pharmacies.

AbbVie is committed to the intended purpose of the 340B program and believes that for the 340B program to fulfill its important mission of improving access to medicines for uninsured and vulnerable patients, the program integrity challenges must be addressed. We look forward to working collaboratively with you to further strengthen the 340B program.

Please reach out to 340bcommunications@abbvie.com if you have questions about our updated policy. For assistance with using 340 ESP™, please contact support@340BESP.com.

Best regards,

Chris Compisi
Vice President, US Market Access

[1] Grantees refers to entities eligible for the 340B program under 42 U.S.C. §256(b)(4)(A)-(K).

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FREQUENTLY ASKED QUESTIONS

Medicines Covered

Q: Which AbbVie medicines are subject to this updated contract pharmacy policy?
The policy applies to the list of products attached to this FAQ. AbbVie will inform covered entities of any changes to the product list. Both the AbbVie policy and the up-to-date list of AbbVie products can be found on 340B ESP™ www.340BESP.com.

Exception for Certain Products

Q: Am I still able to designate a contract pharmacy location for AbbVie medicines subject to a limited distribution network if my covered entity in-house pharmacy is not in the limited distribution network?
If your covered entity's in-house pharmacy is not within a limited distribution network for an AbbVie product, you may designate one of the specified contract pharmacy locations for receiving replenishment shipment of the product. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy location. Currently, this contract pharmacy designation is available for Duopa and Imbruvica. Please access 340B ESP™ at www.340BESP.com and navigate to the Entity Profile tab to make your selection. **Even if you had previously selected a designated one contract pharmacy location for Duopa or Imbruvica under AbbVie's previous policy, your covered entity must still access 340B ESP™ and select one designated pharmacy location for the limited distribution products under this updated policy. Your designated pharmacy location for limited distribution products must be listed in 340B ESP™ by April 9, 2023 for the designation to take effect on April 17, 2023.** If you have questions about how to make this designation, please contact Second Sight Solutions at 888-398-5520 or support@340BESP.com.

Exception for Hospital Covered Entities *Without* an In-House Pharmacy

Q: What if my covered entity does not have an outpatient pharmacy at the location registered as a parent or child site on the 340B covered entity database?
If your covered entity does not have an in-house outpatient pharmacy capable of dispensing 340B priced products, your entity may designate a single contract pharmacy location and AbbVie will facilitate bill to/ ship to replenishment orders of 340B priced drugs to that contract pharmacy; *provided that*:

(i) the covered entity registers with 340B ESP™ and submits limited claims data on 340B utilization for such contract pharmacy, and
(ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site.

Q: How can my covered entity identify pharmacy locations within 40 miles of my parent hospital?
340B ESP™ will maintain a list of pharmacies within a 40 mile radius of the parent hospital registered on the HRSA 340B OPAIS database.

Q: What if I am unable to identify an eligible pharmacy location for my designation? For example, what if there is no pharmacy location within 40 miles of my covered entity's parent site?
AbbVie is committed to ensuring that every covered entity has at least one pharmacy location where it can receive AbbVie's medicines at 340B prices. If you are unable to locate a pharmacy location within 40 miles, AbbVie will work with your covered entity to locate the nearest appropriate contract pharmacy location. Please reach out to 340 ESP™ if you encounter challenges in designating your one contract pharmacy location.

Designation of Permitted Contract Pharmacy Locations

Q: If my covered entity is eligible to designate a contract pharmacy location because it does not have an in-house pharmacy, how does my entity make its designation?
Covered entities that are eligible to designate a single contract pharmacy can do so by registering an account at www.340BESP.com and navigating to the Entity Profile tab. The 340B ESP™ platform is the only way a covered entity can designate its single contract pharmacy location under AbbVie's policy. **The one contract pharmacy location must be listed in 340B ESP™ by April 9, 2023 for the designation to take effect on April 17, 2023. Even if your covered entity has designated an exception for one contract pharmacy location under AbbVie's previous policy or is submitting claims data for the desired location, you must still access 340B ESP™ and select your designated contract pharmacy location for this updated policy. Please do so prior to April 9, 2023.** If you fail to designate your one contract pharmacy location by April 9, 2023, you may still make a designation after such date, but the designated contract pharmacy location will not be eligible for 340B priced orders by the effective date of AbbVie's updated policy.

Once during each 12-month period following the effective date of this policy, a covered entity may designate a different contract pharmacy location. Please note that such designations may take up to 10 business days to become effective.

Q: If I designate one contract pharmacy location to receive orders of medicines subject to this policy, should I also make a separate designation for a contract pharmacy location to receive AbbVie medicines subject to a limited distribution network?
Yes, you should separately designate one contract pharmacy location to receive medicines subject to a limited distribution network. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy. Currently, this separate contract pharmacy designation is available for Duopa and Imbruvica. Accordingly, this pharmacy designation may be in addition to the one permitted contract pharmacy designation for other AbbVie medicines. Please access 340B ESP™ at www.340BESP.com to make this selection.

Q: My covered entity is affiliated with an outpatient pharmacy that is registered with HRSA as a contract pharmacy. How will AbbVie's policy impact this pharmacy location?
AbbVie will decline to facilitate bill to/ ship to orders for all contract pharmacies of hospital covered entities. Your covered entity should place orders for delivery to your covered entity's in-house pharmacy. Hospital covered entities that do not have an in-house pharmacy, may choose to designate

an affiliated contract pharmacy as its designated contract pharmacy location, provided it complies with the data submission and distance requirements described herein.

Claims Data Submission Requirements

Q: What are the requirements for submission of claims data?
The claims data submission requirement applies to a hospital covered entity without an in-house pharmacy that designates one contract pharmacy location within 40 miles of the HRSA registered covered entity parent site. All specified claims data must be submitted within 45 days of the date of dispense to your covered entity's patient. Please submit claims data within the specified time period to ensure your designated contract pharmacy location remains eligible to receive 340B priced medicines. If purchases for the designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines.

The 340B ESP™ platform requires claims uploads on the 1st and 16th of every month. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform. Please see 340B ESP™ at www.340BESP.com for additional details on submitting claims data, including the limited set of required data fields.

Q: How will AbbVie use the 340B claims data that covered entities provide through 340B ESP™?
Contract pharmacy claims data uploaded by 340B covered entities will be used to identify and resolve certain ineligible rebates, including in Medicaid, Medicare Part D, TRICARE and commercial payer rebates, determine compliance with AbbVie's 340B integrity initiative and determine eligibility for placing certain replenishment orders under the policy.

Q: What happens if my organization is unable to provide claims data in conformance with AbbVie's policy?
Failure to provide claims data in conformance with the requirements of this policy may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with questions. Please also ensure that your covered entity's contract pharmacy administrator is aware of these policy requirements and takes any appropriate steps to assist with the submission of claims data. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient. AbbVie will provide covered entities a 60-day grace period from the effective date of this policy to start submitting claims data for the designated contract pharmacy location.

You can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520. Any changes to AbbVie's policy will be available in the most up-to-date policy document on www.340BESP.com.

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AbbVie 340B Program Integrity Initiative Applicable Products

PRODUCT
CREON®
DEPAKOTE®
DUOPA®
GENGRAF®
HUMIRA®
IMBRUVICA®
KALETRA®
K-TAB®
LUPRON®
MAVYRET®
NIASPAN®
NIMBEX®
NORVIR®
ORIAHNN®
ORILISSA®
RINVOQ®
SKYRIZI®
SURVANTA®
SYNTHROID®
TRICOR®
TRILIPIX®
ULTANE®
VIEKIRA PAK®
ZEMPLAR®
ACTONEL®
ACULAR®
ACULAR® LS
ACUVAIL®
ALOCRIL®
ALPHAGAN® P
ANDRODERM®
ARMOUR® THYROID
ASACOL® HD
ATELVIA®
AVYCAZ®
BENTYL®
BOTOX®

PRODUCT
BYSTOLIC®
CANASA®
CARAFATE®
CELEXA®
COMBIGAN®
CONDYLOX®
CRINONE®
DALVANCE®
DELZICOL®
DURYSTA®
ESTRACE®
FETZIMA®
FML®
FML FORTE®
GELNIQUE®
GENERESS® FE
INFED®
KADIAN®
KYBELLA®
LASTACAFT®
LATISSE®
LEXAPRO®
LINZESS®
LO LOESTRIN® FE
LUMIGAN®
MINASTRIN® 24 Fe
MONUROL®
NAMENDA® / NAMENDA XR®
NAMZARIC®
OCUFLOX®
OXYTROL®
OZURDEX®
POLYTRIM®
PRED FORTE®
PRED MILD®
PYLERA®
QULIPTA®
RAPAFLO®
RECTIV®
REFRESH®

PRODUCT
RESTASIS®
SAPHRIS®
SAVELLA®
TAYTULLA®
TEFLARO®
UBRELVY®
URSO FORTE® / URSO 250®
VANIQA®
VIBERZI®
VIIBRYD®
VRAYLAR®
VUITY™
ZYMAXID®

EXHIBIT C

abbvie

April 30, 2024 Update – New Attachment A

Dear 340B Covered Entity,

AbbVie is updating its 340B program integrity initiative to include Venclexta.

AbbVie's initiative is designed to address persistent abuses of the 340B program, including diversion and inappropriate duplicate discounting. AbbVie's initiative does *not* block access to 340B priced medicines for any eligible covered entity and patients will continue to have uninterrupted access to AbbVie's medicines. Under the initiative, AbbVie declines to facilitate bill to/ ship to orders for all hospital covered entities for 340B-priced medicines. This limitation on bill to/ ship to orders in AbbVie's current policy is aligned with AbbVie's standard commercial sales conditions for non-340B customers. Accordingly, hospital covered entities are not permitted to direct delivery of AbbVie's 340B priced medicines to contract pharmacies. AbbVie's 340B integrity initiative will continue to honor bill to/ ship to requests to contract pharmacies for grantee covered entities.

What is new under AbbVie's integrity initiative? Effective May 1, 2024, Venclexta is being added to the list of applicable products included under this program integrity initiative. In addition, AbbVie has updated the FAQ section of our initiative. Please review the attached updated FAQ, which we hope you find easy to understand and apply.

Patients continue to have uninterrupted access to AbbVie medicines. All covered entities are able to purchase 340B priced medicines for delivery to locations properly registered as a 340B covered entity or child site on the HRSA database. Grantee covered entities will still be permitted to utilize contract pharmacies.

What is AbbVie's policy for hospital covered entities? Except for the limited exceptions described below or in the attached FAQs, hospital covered entities are not eligible to place bill to/ ship to replenishment orders of 340B priced medicines for contract pharmacies.

A hospital covered entity *without* an in-house outpatient pharmacy may designate one contract pharmacy location. AbbVie will facilitate bill to/ ship to orders of 340B priced medicines to that location only; provided that, (i) the covered entity submits limited claims data on 340B utilization for such contract pharmacy location and (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

Even if your hospital covered entity had previously designated a contract pharmacy location under AbbVie's existing policy, you will need to access 340B ESP™

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and designate one contract pharmacy location for Venclexta. Please do so prior to April 21, 2024. For details on accessing the exceptions to this policy, please see the attached FAQs.

What is AbbVie's policy for *federal grantee covered entities*? There is **no change** for federal grantee[1] covered entities, such as community health centers, federally-qualified health centers and Ryan White clinics. Federal grantee covered entities will continue to be eligible to place bill to/ ship to replenishment orders of 340B priced drugs for their contract pharmacies.

AbbVie is committed to the intended purpose of the 340B program and believes that for the 340B program to fulfill its important mission of improving access to medicines for uninsured and vulnerable patients, the program integrity challenges must be addressed. We look forward to working collaboratively with you to further strengthen the 340B program.

Please reach out to 340bcommunications@abbvie.com if you have questions about our updated policy. For assistance with using 340 ESP™, please contact support@340BESP.com.

Best regards,

Chris Compisi
Vice President, US Market Access

[1] Grantees refers to entities eligible for the 340B program under 42 U.S.C. §256(b)(4)(A)-(K).

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FREQUENTLY ASKED QUESTIONS

Q: Which AbbVie medicines are subject to this updated contract pharmacy policy?
The policy applies to the list of products attached to this FAQ. AbbVie will inform covered entities of any changes to the product list. Both the AbbVie policy and the up-to-date list of AbbVie products can be found on 340B ESP™ www.340BESP.com.

Q: Am I still able to designate a contract pharmacy location for AbbVie medicines subject to a limited distribution network if my covered entity in-house pharmacy is not in the limited distribution network?
If your covered entity's in-house pharmacy is not within a limited distribution network for an AbbVie product, you may designate one of the specified contract pharmacy locations for receiving replenishment shipment of the product. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy location. This contract pharmacy designation is available for Duopa, Imbruvica, and Venclexta. Please access 340B ESP™ at www.340BESP.com and navigate to the Entity Profile tab to make your selection. **Even if you had previously selected a designated one contract pharmacy location for Duopa or Imbruvica, your covered entity must still access 340B ESP™ and select one designated pharmacy location for Venclexta. Your designated pharmacy location for Venclexta must be listed in 340B ESP™ by April 21, 2024 for the designation to take effect on May 1, 2024.** If you have questions about how to make this designation, please contact Second Sight Solutions at 888-398-5520 or support@340BESP.com.

Q: Does my covered entity have an "in-house pharmacy"?
An "in-house pharmacy" is any type of pharmacy–including but not limited to specialty pharmacy, retail pharmacy, central fill pharmacy, etc. –that (i) is 100% owned by your covered entity, (ii) is appropriately licensed or authorized by the applicable state, (iii) can dispense the list of products attached to this FAQ; and (iv) is not listed as a contract pharmacy for your covered entity on OPAIS.

It does not include a pharmacy partially owned by your covered entity, a pharmacy owned by an entity other than your covered entity, including a parent or affiliated entity other than your covered entity. Merely listing a non-entity owned pharmacy (i.e., a contract pharmacy) as a ship to address on OPAIS does not confer entity-owned status on the pharmacy. AbbVie may require eligibility information, such as auditable records, to confirm 100% ownership by your covered entity.

For purposes of clarity, if your covered entity has an "in-house pharmacy" as explained above, the entity **may not** designate a contract pharmacy.

Q: What if my covered entity does not have an in-house outpatient pharmacy at the location registered as a parent or child site on the 340B covered entity database?

If your covered entity does not have an in-house outpatient pharmacy capable of dispensing covered outpatient drugs, your covered entity may designate a single contract pharmacy location. AbbVie will facilitate bill to/ ship to replenishment orders of 340B priced drugs to that contract pharmacy; *provided that*:

(i) your covered entity registers with 340B ESP™ and completes the attestation;
(ii) your covered entity provides AbbVie with appropriate documentation subject to AbbVie's sole discretion to support that your covered entity does not have an in-house pharmacy capable of dispensing 340B priced products;
(iii) your covered entity submits limited claims data on 340B utilization for such contract pharmacy (see below for more details), and
(iv) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site.

Q: Can child sites also designate a single contract pharmacy?
No. A child site must utilize the parent site's contract pharmacy designation. AbbVie considers all sites together as one covered entity, inclusive of the parent and child sites, listed on the HRSA database.

Q: How can my covered entity identify pharmacy locations within 40 miles of my parent hospital?
340B ESP™ will maintain a list of pharmacies within a 40 mile radius of the parent hospital registered on the HRSA 340B OPAIS database.

Q: What if I am unable to identify an eligible pharmacy location for my designation? For example, what if there is no pharmacy location within 40 miles of my covered entity's parent site?
AbbVie is committed to ensuring that every covered entity has at least one pharmacy location where it can receive AbbVie's medicines at 340B prices. If you are unable to locate a pharmacy location within 40 miles, AbbVie will work with your covered entity to locate the nearest appropriate contract pharmacy location. Please reach out to 340 ESP™ if you encounter challenges in designating your one contract pharmacy location.

Q: If my covered entity is eligible to designate a contract pharmacy location because it does not have an in-house pharmacy, how does my entity make its designation?
Covered entities that are eligible to designate a single contract pharmacy can do so by registering an account at www.340BESP.com and navigating to the Entity Profile tab. The 340B ESP™ platform is the only way a covered entity can designate its single contract pharmacy location under AbbVie's policy. **If you are eligible for the one contract pharmacy exception, you must access 340B ESP™ and select your designated contract pharmacy location for Venclexta's limited distribution network. Please designate the one contract pharmacy location for Venclexta prior to April 21, 2024 to ensure it is effective by May 1, 2024.** If you fail to designate your one contract pharmacy location for Venclexta by

April 21, 2024, you may still make a designation after such date, but the designated contract pharmacy location will not be eligible for 340B priced orders of Venclexta starting May 1, 2024.

Once during each 12-month period following the effective date of this policy, a covered entity may designate a different contract pharmacy location. Please note that such designations may take up to 10 business days to become effective.

Please note that designating a contract pharmacy does not in any way eliminate the program eligibility requirements and provide access to pricing to entities or individuals that do not meet the terms of this initiative. Covered entities are responsible for ensuring that their particular contracting arrangements and operations conform to the requirements of all applicable laws and regulations.

Q: Does my covered entity need to have a HIN registered for the contract pharmacy that they designate?
Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for AbbVie to manage its process with its wholesalers. If you try to designate a contract pharmacy location that does not have a HIN in 340B ESP™, the system will provide guidance on how to you can register the pharmacy for a HIN. If you have previously registered a contract pharmacy without a HIN, 340B ESP™ will notify you if such information needs to be updated. If you have questions, please reach out to support@340BESP.com.

Q: If I designate one contract pharmacy location to receive orders of medicines subject to this policy, should I also make a separate designation for a contract pharmacy location to receive AbbVie medicines subject to a limited distribution network?
Yes, you should separately designate one contract pharmacy location to receive medicines subject to a limited distribution network. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy. Currently, this separate contract pharmacy designation is available for Duopa, Imbruvica and Venclexta. Accordingly, this pharmacy designation may be in addition to the one permitted contract pharmacy designation for other AbbVie medicines. Please access 340B ESP™ at www.340BESP.com to make this selection.

Q: My covered entity is affiliated with an outpatient pharmacy that is registered with HRSA as a contract pharmacy. How will AbbVie's policy impact this pharmacy location?
AbbVie will decline to facilitate bill to/ ship to orders for all contract pharmacies of hospital covered entities. Your covered entity should place orders for delivery to your covered entity's in-house pharmacy. Hospital covered entities that do not have an in-house pharmacy may choose to designate an affiliated contract pharmacy as its designated contract pharmacy location, provided it complies with the data submission and distance requirements described herein.

Q: What are the requirements for submission of claims data?
The claims data submission requirement applies to a hospital covered entity without an in-house pharmacy that designates one contract pharmacy location within 40 miles of the HRSA registered covered entity parent site. All specified claims data must be submitted within 45 days of the date of dispense to your covered entity's patient. Please submit claims data within the specified time period to ensure your designated contract pharmacy location remains eligible to receive 340B priced medicines. If purchases for the designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines.

The 340B ESP™ platform requires claims uploads on the 1st and 16th of every month. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform. Please see 340B ESP™ at www.340BESP.com for additional details on submitting claims data, including the limited set of required data fields.

Q: How will AbbVie use the 340B claims data that covered entities provide through 340B ESP™?
Contract pharmacy claims data uploaded by 340B covered entities will be used to identify and resolve certain ineligible rebates (including in Medicaid, Medicare Part D, TRICARE and commercial payer rebates), determine compliance with AbbVie's 340B integrity initiative, and determine eligibility for placing certain replenishment orders under the policy.

Q: What happens if my organization is unable to provide claims data in conformance with AbbVie's policy?
Failure to provide claims data in conformance with the requirements of this policy may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with questions. Please also ensure that your covered entity's contract pharmacy administrator is aware of these policy requirements and takes any appropriate steps to assist with the submission of claims data. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient.

Q: May a covered entity designate a single contract pharmacy 'replenishment' location, include dispensing activity from several other non-designated contract pharmacy locations of the same organization, and then create replenishment orders based on all the dispensing activity to a single replenishment location?
No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and location. All dispensing to eligible patients must occur at the properly designated contract pharmacy location(s), and 340B priced drugs will be shipped directly to that location either by AbbVie or an authorized distributor.

Q: May my covered entity tally dispensing activity from non-designated contract pharmacy locations and/ or a non-eligible pharmacy locations and place subsequent orders to be shipped to a different, single designated contract pharmacy or covered entity in-house location?
No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and physical location, and 340B dispensing activity must occur at this location in order for the location to receive 340B priced drugs. Covered entities may not resell or otherwise transfer 340B covered outpatient drugs to a person who is not a patient of the covered entity.

Q: What if two covered entities attempt to order a 340B priced drug to replace the same prescription number or unit dispensed?
Multiple 340B requests on a single prescription (same prescription ID number) or unit will not be allowed. AbbVie will honor the first 340B discount request received and deny all subsequent requests.

Q: Is there a time limitation on when replenishment orders can be placed to my designated contract pharmacy?
If the contract pharmacy has submitted claims data within 45 days of the date of dispensation by the contract pharmacy, AbbVie will process the contract pharmacy's replenishment order.

You can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520. Any changes to AbbVie's policy will be available in the most up-to-date policy document on www.340BESP.com.

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Attachment A
State Policies

Arkansas: AbbVie's 340B program integrity initiative does not apply to covered entities in Arkansas.

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AbbVie 340B Program Integrity Initiative Applicable Products

PRODUCT
ANDROGEL®
CREON®
DEPAKOTE®
DUOPA®
GENGRAF®
HUMIRA®
IMBRUVICA®
KALETRA®
K-TAB®
LUPRON®
MAVYRET®
NIASPAN®
NIMBEX®
NORVIR®
ORIAHNN®
ORILISSA®
RINVOQ®
SKYRIZI®
SURVANTA®
SYNTHROID®
TRICOR®
TRILIPIX®
ULTANE®
VIEKIRA PAK®
ZEMPLAR®
ACTONEL®
ACULAR®
ACULAR® LS
ACUVAIL®
ALOCRIL®
ALPHAGAN® P
ANDRODERM®
ARMOUR® THYROID
ASACOL® HD

PRODUCT
ATELVIA®
AVYCAZ®
BENTYL®
BOTOX®
BYSTOLIC®
CANASA®
CARAFATE®
CELEXA®
COMBIGAN®
CONDYLOX®
CRINONE®
DALVANCE®
DELZICOL®
DURYSTA®
ESTRACE®
FETZIMA®
FML®
FML FORTE®
GELNIQUE®
GENERESS® FE
INFED®
KADIAN®
KYBELLA®
LASTACAFT®
LATISSE®
LEXAPRO®
LINZESS®
LO LOESTRIN® FE
LUMIGAN®
MINASTRIN® 24 Fe
MONUROL®
NAMENDA® / NAMENDA XR®
NAMZARIC®
OCUFLOX®
OXYTROL®
OZURDEX®

PRODUCT
POLYTRIM®
PRED FORTE®
PRED MILD®
PYLERA®
QULIPTA®
RAPAFLO®
RECTIV®
REFRESH®
RESTASIS®
SAPHRIS®
SAVELLA®
TAYTULLA®
TEFLARO®
UBRELVY®
URSO FORTE® / URSO 250®
VENCLEXTA®
VIBERZI®
VIIBRYD®
VRAYLAR®
VUITY™
ZYMAXID®

EXHIBIT D

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February 27, 2025 – Updated Attachment A

Dear 340B Covered Entity,

Effective immediately, AbbVie is updating its 340B program integrity initiative to include Elahere® and Vyalev® in the list of AbbVie products subject to restriction. This change applies to both hospital and grantee covered entity types.

AbbVie's 340B program integrity initiative is designed to address persistent abuse of the 340B program, including diversion and inappropriate duplicate discounting. AbbVie's initiative does *not* block access to 340B priced medicines for any eligible covered entity and patients will continue to have uninterrupted access to AbbVie's medicines.

Under the initiative, AbbVie will decline to facilitate bill to/ ship to orders for all covered entity types for 340B-priced medicines. This limitation on bill to/ ship to orders is aligned with AbbVie's standard commercial sales conditions for non-340B customers. Accordingly, covered entities are not permitted to direct orders of AbbVie's 340B priced medicines to contract pharmacies, unless so provided under the limited conditions of this policy.

What is new under AbbVie's integrity initiative? Effective February 27, 2025, Elahere and Vyalev are being added to the list of applicable products included under this program integrity initiative. In addition, AbbVie has updated the FAQ section of our initiative. Please review the attached updated FAQ, which we hope you find easy to understand and apply.

Patients will continue to have uninterrupted access to AbbVie medicines, including Vyalev and Elahere. All covered entities are able to purchase 340B priced medicines for delivery to locations properly registered as a 340B covered entity or child site on the HRSA database to be dispensed from those sites.

What is AbbVie's policy for <u>grantee</u> covered entities? "Grantee" covered entity types listed in 42 U.S.C. §256(b)(4)(A)-(K) that wish to utilize contract pharmacies must register with 340B ESP™, a web-based platform made available to covered entities at no cost, and submit requested claims data. AbbVie will use this claims data to identify ineligible or duplicate discounts. Grantee covered entities that elect not to register or provide the required claims data for a contract pharmacy will not be able to place bill to/ ship to orders of 340B priced drugs. Grantee covered entities that register and provide data will be able to use an unlimited number of contract pharmacies. Please refer to the Next Steps on page 3 and Frequently Asked Questions for Grantee Covered Entities on page 8 below.

What is AbbVie's policy for <u>hospital</u> covered entities? Except for the limited exceptions described below or in the attached FAQs, hospital covered entities may not place bill to/ ship to orders of 340B priced medicines for contract pharmacies.

A hospital covered entity *without* an in-house outpatient pharmacy may designate a single contract pharmacy location. AbbVie will facilitate bill to/ ship to orders of 340B priced medicines to that location only; provided that, (i) the covered entity submits limited claims data

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on 340B utilization for such contract pharmacy location and (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative. Please refer to the Frequently Asked Questions for Hospital Covered Entities on page 4 below.

AbbVie is committed to the intended purpose of the 340B program. If the 340B program is to fulfill its important mission of improving access to medicines for uninsured and vulnerable patients, program integrity challenges must be addressed. We look forward to working collaboratively with you to further strengthen the 340B program.

Please reach out to 340Bcommunications@abbvie.com if you have questions about our updated policy. For assistance with using 340 ESP™, please contact support@340BESP.com.

Best regards,

Edward Scheidler
Head of 340B Center of Excellence

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NEXT STEPS FOR COVERED ENTITIES

To get started with the 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes about 15 minutes.

2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.

3. Login to 340B ESP™ and submit your 340B contract pharmacy claims data twice monthly. Once your account is set up, the claims upload process takes about 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520. Any changes to AbbVie's policy will be available in the most up-to-date policy document on www.340BESP.com.

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FREQUENTLY ASKED QUESTIONS FOR HOSPITAL COVERED ENTITIES

Except in certain limited instances, hospital covered entities are not eligible to place bill to/ ship to replenishment orders of 340B priced medicines for contract pharmacies.

A hospital covered entity *without* an in-house outpatient pharmacy may designate one contract pharmacy location. AbbVie will facilitate bill to/ ship to orders of 340B priced medicines to that location only; provided that: (i) the covered entity submits limited claims data on 340B utilization for such contract pharmacy location and (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

Q: Which AbbVie medicines are subject to this updated contract pharmacy policy?
The policy applies to the list of products attached to this FAQ. AbbVie will announce any changes to the product list. Both the AbbVie policy and the up-to-date list of AbbVie products can be found on 340B ESP™ website, www.340BESP.com.

Q: Am I still able to designate a contract pharmacy location for AbbVie medicines subject to a limited distribution network if my covered entity in-house outpatient pharmacy is not in the limited distribution network?
Yes. If your hospital covered entity's in-house outpatient pharmacy is not within a limited distribution network for an AbbVie product, you may designate one of the specified contract pharmacy locations for receiving replenishment shipment of the product. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy location. This contract pharmacy designation is available for Duopa, Elahere, Imbruvica, Venclexta, and Vyalev. Please access 340B ESP™ at www.340BESP.com and navigate to the Entity Profile tab to make your selection. **Even if you had previously selected a designated one contract pharmacy location for Duopa, Imbruvica, or Venclexta, your covered entity must still access 340B ESP™ and select one designated pharmacy location for Elahere or Vyalev (or both). Your designated pharmacy location for Elahere and/or Vyalev must be listed in 340B ESP™ by March 9, 2025 for the designation to take effect on March 18, 2025.** If you have questions about how to make this designation, please contact Second Sight Solutions at 888-398-5520 or support@340BESP.com.

Q: Does my hospital covered entity have an "in-house outpatient pharmacy"?
An "in-house outpatient pharmacy" is any type of pharmacy–including but not limited to specialty pharmacy, retail pharmacy, or central fill pharmacy, that (i) is 100% owned by your covered entity, (ii) is appropriately licensed or authorized by the applicable state, (iii) is capable of dispensing covered outpatient drugs; and (iv) is not listed as a contract pharmacy for your covered entity on OPAIS.

It does not include a pharmacy partially owned by your covered entity, a pharmacy owned by an entity other than your covered entity, including a parent or affiliated entity other than your covered entity. Merely listing a non-entity owned pharmacy (i.e., a contract pharmacy) as a ship to address on OPAIS does not confer entity-owned status on the pharmacy. AbbVie may require eligibility information, such as auditable records, to confirm 100% ownership by your covered entity.

For purposes of clarity, if your covered entity has an "in-house outpatient pharmacy" as explained above, the entity **may not** designate a contract pharmacy.

Q: What if my hospital covered entity does not have an in-house outpatient pharmacy at the location appropriately registered as a parent or child site on the 340B covered entity database?

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If your hospital covered entity does not have an in-house outpatient pharmacy capable of dispensing covered outpatient drugs, your hospital covered entity may designate a single contract pharmacy location. AbbVie will facilitate bill to/ ship to replenishment orders of 340B priced drugs to that contract pharmacy; *provided that*:

(i) your hospital covered entity registers with 340B ESP™ and completes the attestation;
(ii) your hospital covered entity provides AbbVie with appropriate documentation subject to AbbVie's sole discretion to support that your covered entity does not have an in-house outpatient pharmacy capable of dispensing covered outpatient drugs;
(iii) your hospital covered entity submits limited claims data on 340B utilization for such contract pharmacy (see below for more details), and
(iv) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site.

Q: What if my in-house outpatient pharmacy is capable of purchasing and dispensing 340B priced drugs but is not used to dispense AbbVie drugs or my hospital covered entity prefers to utilize a contract pharmacy. Is my hospital covered entity eligible to designate a contract pharmacy?
No. If your hospital covered entity has an in-house outpatient pharmacy capable of purchasing at the 340B price and dispensing, the covered entity is not eligible to also designate a contract pharmacy.

Q: Can child sites also designate a single contract pharmacy?
No. A child site must utilize the parent hospital site's contract pharmacy designation. AbbVie considers all sites together as one covered entity, inclusive of the parent and child sites, listed on the HRSA database.

Q: How can my hospital covered entity identify pharmacy locations within 40 miles of my parent hospital?
340B ESP™ will maintain a list of pharmacies within a 40-mile radius of the parent hospital registered on the HRSA 340B OPAIS database.

Q: What if I am unable to identify an eligible pharmacy location for my designation? For example, what if there is no pharmacy location within 40 miles of my covered entity's parent site?
AbbVie is committed to ensuring that every covered entity has at least one pharmacy location where it can receive AbbVie's medicines at 340B prices. If you are unable to locate a pharmacy location within 40 miles, AbbVie will work with your covered entity to locate the nearest appropriate contract pharmacy location. Please reach out to 340 ESP™ if you encounter challenges in designating your one contract pharmacy location.

Q: If my hospital covered entity is eligible to designate a contract pharmacy location because it does not have an in-house outpatient pharmacy, how does my hospital entity make its designation?
Hospital covered entities that are eligible to designate a single contract pharmacy can do so by registering an account at www.340BESP.com and navigating to the Entity Profile tab. The 340B ESP™ platform is the only way a covered entity can designate its single contract pharmacy location under AbbVie's policy.

Once during each 12-month period following the effective date of this policy, a covered entity may designate a different contract pharmacy location. Please note that such designations may take up to 10 business days to become effective.

Please note that designating a contract pharmacy does not in any way eliminate the program eligibility requirements and provide access to pricing to entities or individuals that do not meet the terms of this initiative. Hospital covered entities are responsible for ensuring that their particular contracting arrangements and operations conform to the requirements of all applicable laws and regulations.

Q: Does my covered entity need to have a HIN registered for the contract pharmacy that they designate?

Yes, a contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy. This information is important for AbbVie to manage its process with its wholesalers. If you try to designate a contract pharmacy location that does not have a HIN in 340B ESP™, the system will provide guidance on how the contract pharmacy can be assigned a HIN. If you have previously registered a contract pharmacy without a HIN, 340B ESP™ will notify you if such information needs to be updated. If you have questions, please reach out to support@340BESP.com.

Q: If I designate one contract pharmacy location to receive orders of medicines subject to this policy, may I also make a separate designation for a contract pharmacy location to receive AbbVie medicines subject to a limited distribution network?
Yes, you may separately designate one contract pharmacy location to receive medicines subject to a limited distribution network. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy. Currently, this separate contract pharmacy designation is available for Duopa, Elahere, Imbruvica, Venclexta, and Vyalev. Accordingly, this pharmacy designation may be in addition to the one permitted contract pharmacy designation for other AbbVie medicines. Please access 340B ESP™ at www.340BESP.com to make this selection.

Q: My hospital covered entity is affiliated with an outpatient pharmacy that is registered with HRSA as a contract pharmacy. How will AbbVie's policy impact this pharmacy location?
AbbVie will decline to facilitate bill to/ ship to orders for all contract pharmacies of hospital covered entities other than those identified in this policy. Your covered entity should place orders for delivery to your covered entity's in-house outpatient pharmacy. Hospital covered entities that do not have an in-house outpatient pharmacy may choose to designate an affiliated contract pharmacy as its sole designated contract pharmacy location, provided it complies with the data submission and distance requirements described herein.

Q: What are the requirements for submission of claims data for hospital covered entities?
The claims data submission requirement applies to hospital covered entities without an in-house outpatient pharmacy that designate one contract pharmacy location within 40 miles of the HRSA registered covered entity parent site. All specified claims data must be submitted within 45 days of the date of dispense to your covered entity's patient. Please submit claims data within the specified time period to ensure your designated contract pharmacy location remains eligible to receive 340B priced medicines. If purchases for the designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines.

The 340B ESP™ platform requires claims uploads on the 1st and 16th of every month. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform. Please see 340B ESP™ at www.340BESP.com for additional details on submitting claims data, including the limited set of required data fields.

Q: How will AbbVie use the 340B claims data that covered entities provide through 340B ESP™?
Contract pharmacy claims data uploaded by 340B covered entities will be used to identify and resolve certain ineligible rebates (including in Medicaid, Medicare Part D, TRICARE, commercial payer rebates, and multiple 340B rebate requests on a single dispense), determine compliance with AbbVie's 340B integrity initiative, and determine eligibility for placing certain 340B orders under the policy. Only one covered entity may claim the 340B discount on each 340B-eligible dispense.

Q: What happens if my hospital covered entity is unable to provide claims data in conformance with AbbVie's policy?
Failure to provide claims data in conformance with the requirements of this policy may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with questions. Please also ensure that your covered

entity's contract pharmacy administrator is aware of these policy requirements and takes any appropriate steps to assist with the submission of claims data. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient.

Q: May a hospital covered entity designate a single contract pharmacy 'replenishment' location, include dispensing activity from several other non-designated contract pharmacy locations of the same organization, and then create replenishment orders based on all the dispensing activity to a single replenishment location?
No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and location. All dispensing to eligible patients must occur at the properly designated contract pharmacy location(s), and 340B priced drugs will be shipped directly to that location either by AbbVie or an authorized distributor.

Q: May my hospital covered entity tally dispensing activity from non-designated contract pharmacy locations and/ or a non-eligible pharmacy locations and place subsequent orders to be shipped to a different, single designated contract pharmacy or covered entity in-house location?
No. Contract pharmacy designations are specific to a location registered individually on the HRSA database by name and physical location, and 340B dispensing activity must occur at this location in order for the location to receive 340B priced drugs. Covered entities may not resell or otherwise transfer 340B covered outpatient drugs to a person who is not a patient of the covered entity.

Q: What if two covered entities attempt to order a 340B priced drug to replace the same prescription number or unit dispensed?
Multiple 340B requests on a single prescription (same prescription ID number) or unit will not be allowed. AbbVie will honor the first 340B discount request received and deny all subsequent requests.

Q: May my hospital covered entity (or my contract pharmacy) accept delivery of 340B-priced AbbVie drugs and ship them to another entity?
No. Consistent with federal wholesaling and redistribution laws, and AbbVie's standard sales terms and conditions, medicines may be purchased solely for the use by the purchasing entity. This excludes selling, transferring, or otherwise distributing product to any person or entity for resale or other purposes.

Q: Is there a time limitation on when orders can be placed to my designated contract pharmacy?
If the contract pharmacy has submitted claims data within 45 days of the date of dispensation by the contract pharmacy, AbbVie will process the contract pharmacy's order request.

You can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520. Any changes to AbbVie's policy will be available in the most up-to-date policy document on www.340BESP.com.

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FREQUENTLY ASKED QUESTIONS FOR GRANTEE COVERED ENTITIES

Q: Which AbbVie medicines are subject to this updated contract pharmacy policy?
The policy applies to the list of products attached to this FAQ. AbbVie will announce any changes to the product list. Both the AbbVie policy and the up-to-date list of AbbVie products can be found on 340B ESP™ www.340BESP.com.

Q: What if my grantee covered entity would like to utilize or continue to utilize contract pharmacy arrangements?
AbbVie's 340B integrity initiative will honor grantee covered entities' bill to/ ship to requests for an unlimited number of contract pharmacies, *provided that*:

(i) your 340B grantee covered entity registers with 340B ESP™ and your account is activated; and
(ii) your 340B grantee covered entity submits limited claims data by the required date on 340B utilization for each contract pharmacy utilized (see below for more details).

Q: May my grantee covered entity utilize a contract pharmacy that is more than 40 miles from my location?
Yes. Grantee contract pharmacies are not restricted to the 40-mile radius that is a condition for hospital covered entity contract pharmacies.

Q: Does my grantee covered entity need to have a HIN registered for each contract pharmacy it utilizes?
Yes, a contract pharmacy must have a HIN assigned to it for a grantee covered entity to utilize it as a contract pharmacy. This information is important for AbbVie to manage its process with its wholesalers. If you try to utilize a contract pharmacy location that does not have a HIN in 340B ESP™, the system will provide guidance on how the contract pharmacy can be assigned a HIN. If you have previously registered a contract pharmacy without a HIN, 340B ESP™ will notify you if such information needs to be updated. If you have questions, please reach out to support@340BESP.com.

Q: Is my grantee covered entity required to designate one contract pharmacy location for AbbVie medicines subject to a limited distribution network?
No. You may continue to use the contract pharmacy location(s) within the applicable limited distribution network for receiving shipment of the applicable product, subject to the terms of this policy, such as timely submission of specified claims data. The AbbVie medicines available through a limited distribution network: 1) Duopa; 2) Elahere; 3) Imbruvica; 4) Venclexta; and 5) Vyalev. If you have questions, please reach out to support@340BESP.com.

Q: What are the requirements for submission of claims data for grantee covered entities?
All specified claims data must be submitted within 45 days of the date of dispense to your covered entity's patient. Please submit claims data within the specified period to ensure your contract pharmacy locations remain eligible to receive 340B priced medicines. If purchases for a contract pharmacy location exceed conforming claims submitted according to this policy, this may result in that contract pharmacy losing eligibility to receive 340B priced medicines.

The 340B ESP™ platform requires claims uploads on the 1st and 16th of every month. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform. Please see 340B ESP™ at www.340BESP.com for additional details on submitting claims data, including the limited set of required data fields.

Q: What happens if a covered entity that is already registered on the platform misses a data submission date?

If you miss a data submission date, please submit your data as soon as you are able. If a covered entity is repeatedly unable to provide required data in a timely manner, AbbVie may no longer facilitate bill to/ ship to contract pharmacy replenishment orders on 340B claims.

Q: Is my grantee covered entity limited to utilizing a single contract pharmacy?
No, provided your grantee covered entity takes the reasonable step to register with 340B ESP™ and continuously submit limited claims data on your 340B contract pharmacy utilization, you will continue to be able to use bill to/ ship to arrangements for AbbVie products with an **unlimited** number of contract pharmacies.

Q: How will AbbVie use the 340B claims data that covered entities provide through 340B ESP™?
Contract pharmacy claims data uploaded by 340B covered entities will be used to identify and resolve certain ineligible rebates (including in Medicaid, Medicare Part D, TRICARE, commercial payer rebates, and multiple 340B rebate requests on a single dispense), determine compliance with AbbVie's 340B integrity initiative, and determine eligibility for placing certain replenishment orders under the policy. Only one covered entity may claim the 340B discount on each 340B-eligible dispense.

Q: How do I get my contract pharmacy set up to meet the new requirements?
We do not anticipate any action being necessary on the part of contract pharmacies as this policy requires grantee covered entities to submit data for its contract pharmacy utilization. Grantee covered entities must register with the http://www.340BESP.com website and follow instructions to begin submitting data.

Q: What happens if my grantee covered entity does not provide 340B contract pharmacy claims data by the required date? 340B grantees that elect not to provide 340B claims data will no longer be able to place bill to/ ship to 340B orders for AbbVie products dispensed through a contract pharmacy.

Q: What training and resources will be provided to grantee covered entities to help with this transition?
Detailed information about how to use the 340B ESP™ platform can be found at www.340BESP.com/FAQS or email support@340BESP.com. The 340B ESP™ website includes video tutorials and answers to frequently asked questions.

Q: Is AbbVie requiring data for in-house outpatient pharmacies that are registered with HRSA as a covered entity?
No. AbbVie is only requiring 340B grantee covered entities to provide 340B claims data on units dispensed by contract pharmacies. Grantee covered entities do not need to provide 340B claims data for prescriptions filled in their own in-house outpatient pharmacies.

Q: What happens if my grantee covered entity is unable to provide claims data in conformance with AbbVie's policy?
Failure to provide claims data in conformance with the requirements of this policy may result in your contract pharmacies losing eligibility to receive 340B priced medicines. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with questions. Please also ensure that your covered entity's contract pharmacy administrator is aware of these policy requirements and takes any appropriate steps to assist with the submission of claims data. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient.

Q: May my grantee covered entity utilize a single contract pharmacy 'replenishment' location, include dispensing activity from several other contract pharmacy locations of the same organization, and then create replenishment orders based on all the dispensing activity to a single replenishment location?

No. A contract pharmacy is specific to the location registered individually on the HRSA database by name and location. All dispensing to eligible patients must occur at the properly designated contract pharmacy location(s), and 340B priced drugs will be shipped directly to that location either by AbbVie or an authorized distributor.

Q: May my grantee covered entity tally dispensing activity from contract pharmacy locations and/ or a non-eligible pharmacy locations and place subsequent orders to be shipped to a different, individual contract pharmacy or covered entity in-house or ship to location?
No. A contract pharmacy is specific to a location registered individually on the HRSA database by name and physical location, and 340B dispensing activity must occur at this location in order for the location to receive 340B priced drugs. Covered entities may not resell or otherwise transfer 340B covered outpatient drugs to a person who is not a patient of the covered entity.

Q: What if two covered entities attempt to order a 340B priced drug to replace the same prescription number or unit dispensed?
Multiple 340B requests on a single prescription (same prescription ID number) or unit will not be allowed. AbbVie will honor the first 340B discount request received and deny all subsequent requests.

Q: May my grantee covered entity (or my contract pharmacy) accept delivery of 340B-priced AbbVie drugs and ship them to another entity?
No. Consistent with federal wholesaling and redistribution laws, and AbbVie's standard sales terms and conditions, medicines may be purchased solely for the use by the purchasing entity. This excludes selling, transferring, or otherwise distributing product to any person or entity for resale or other purposes.

Q: Is there a time limitation on when orders can be placed to my registered contract pharmacy?
If the grantee covered entity has submitted claims data within 45 days of the date of dispensation by the contract pharmacy, AbbVie will process the contract pharmacy's order request.

You can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520. Any changes to AbbVie's policy will be available in the most up-to-date policy document on www.340BESP.com.

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Attachment A
State Policies

Arkansas: AbbVie's 340B program integrity initiative does not apply to covered entities in Arkansas.

Maryland: Covered entities located in Maryland may access 340B pricing at an unlimited number of contract pharmacies by submitting limited claims data through the 340B ESP™ platform for each of the covered entity's contract pharmacy arrangements. Covered entities in Maryland must submit claims data within 45 days of the date of dispensation by the contract pharmacy.

Minnesota: AbbVie's 340B program integrity initiative does not apply to covered entities in Minnesota.

Mississippi: AbbVie's 340B program integrity initiative does not apply to covered entities in Mississippi.

Missouri: AbbVie's 340B program integrity initiative does not apply to covered entities in Missouri.

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AbbVie 340B Program Integrity Initiative Applicable Products

PRODUCT
ACTONEL®
ACULAR®
ACULAR® LS
ACUVAIL®
ALPHAGAN® P
ANDROGEL®
ARMOUR®THYROID
ATELVIA®
AVYCAZ®
BENTYL®
BOTOX®
BYSTOLIC®
CANASA®
CARAFATE®
CELEXA®
COMBIGAN®
CONDYLOX®
CREON®
CRINONE®
DALVANCE®
DELZICOL®
DEPAKOTE®
DUOPA®
DURYSTA®
ELAHERE®
ESTRACE®
FETZIMA®
FML FORTE®
FML®
GENERESS® FE
GENGRAF®
HUMIRA®
IMBRUVICA®
INFED®
KALETRA®
K-TAB®
KYBELLA®
LASTACAFT®
LATISSE®
LEXAPRO®

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PRODUCT
LINZESS®
LO LOESTRIN® FE
LUMIGAN®
LUPRON®
MAVYRET®
NAMENDA® / NAMENDA XR®
NAMZARIC®
NORVIR®
OCUFLOX®
ORIAHNN®
ORILISSA®
OXYTROL®
OZURDEX®
PRED FORTE®
PRED MILD®
PYLERA®
QULIPTA®
RAPAFLO®
RECTIV®
REFRESH®
RESTASIS®
RINVOQ®
SAPHRIS®
SAVELLA®
SKYRIZI®
SURVANTA®
SYNTHROID®
TAYTULLA®
TEFLARO®
TRICOR®
TRILIPIX®
UBRELVY®
ULTANE®
URSO FORTE® / URSO 250®
VENCLEXTA®
VIBERZI®
VIIBRYD®
VRAYLAR®
VUITY®
VYALEV®
ZEMPLAR®